

# SOUTH CAROLINA'S CERTIFICATE OF NEED PROGRAM



## INTRODUCTION

During the Great Depression and World War II few new hospitals were built in the United States. Yet a large number of communities had no hospital, and many existing hospitals were quickly becoming obsolete. In response, individual communities began to organize planning and fund-raising efforts to build hospitals. Community planning efforts became particularly important in 1946 with the passage of the federal Hill-Burton Act, which provided federal subsidies for hospital construction and promoted local planning based on local needs.

The availability of Hill-Burton funds created a federally-sponsored, 30-year hospital bed construction boom. As a result state and federal governments found themselves faced with both skyrocketing medical costs and a continuing uneven distribution of medical services.

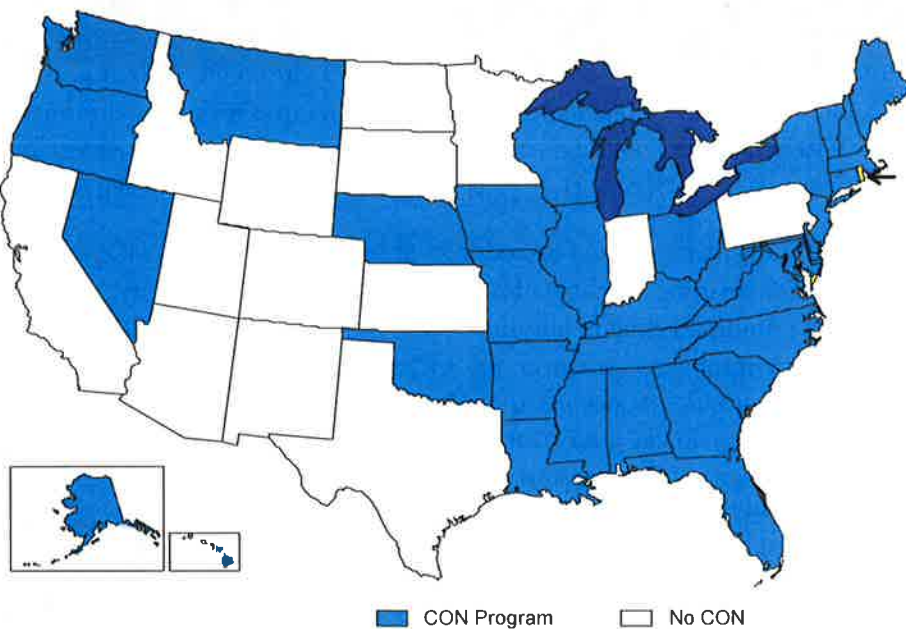
Under third party fee-for-service insurance agreements, which dominated health care financing, providers were reimbursed on a per diem basis and revenues were tied to the number of services provided. Also, providers suffered little risk of overbuilding because they were reimbursed for investment costs. These financial incentives to build and provide more services led to the first state certificate of need (CON) programs in the 1960's and early 1970's as states sought to control costs by regulating capital investments in health care.

During the 1970s the federal government encouraged states to control rising health care costs by managing the growth of health care services and facilities through health planning. In 1974, federal standards were established and federal funds were authorized to support state CON programs through the National Health Planning and Resources Development Act (P.L. 93-641). While some states implemented CON to contain costs, improve access, or monitor quality, others implemented a CON program simply to meet federal requirements. By 1980, all but one state (Louisiana) had a CON program.

In 1982, the federal government began to reduce its control and funding of state CON programs, giving states the freedom to set their own capital expenditure review thresholds or to abolish their CON programs altogether. In 1986, the federal health planning law was repealed, removing the federal government from any role in state CON programs. Most states that repealed CON did so during the latter part of the 1980's. Some states reported growth in services and buildings following repeal, while others noticed little change. In several of the states without a CON program, including Wisconsin, Kansas, Minnesota, and Colorado, numerous attempts have been made to reestablish CON over the years. Today, in spite of the lack of a federal mandate, thirty-six (36) states, the District of Columbia and Puerto Rico continue to have CON programs.

In South Carolina the list of projects requiring a CON has been revised and updated periodically over the years in an effort to make the program as effective as possible in controlling health care costs and assuring access to quality medical services to all South Carolinians.

**CON Regulation by State**



Source: AHPA, National CON Survey

The purpose of this paper is to outline South Carolina's CON law and present arguments for maintaining a state health planning process and certificate of need program. We have, in a separate document, provided recommendations for improving the current system.

## DEFINITION OF CON

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Certificate of Need (CON) is a regulatory review process that requires certain health care providers, such as hospitals and nursing homes, to obtain authorization from the state before making major capital expenditures, acquiring high cost medical equipment or expanding medical services. In South Carolina, the CON Program is governed by Section 44-7-110 through Section 44-7-340 of the South Carolina Code of Laws. Regulation No. 61-15 Certification of Need for Health Facilities and Services was promulgated to provide additional detail.

The purposes of CON are to:

- promote health care cost containment;
- prevent unnecessary duplication of health care facilities and services;
- guide the establishment of health facilities and services that will best serve public needs; and
- ensure that high quality services are provided in health facilities in South Carolina.

South Carolina's CON law:

- requires that a CON be issued to a health care provider planning any construction project or addition of services described in the law;
- establishes procedures and criteria for submitting and reviewing a CON application prior to issuance of a CON;
- requires the state to prepare and publish at least every two years a State Health Plan that outlines the need for medical facilities and services throughout the state and the criteria for reviewing proposed projects under the CON Program; and
- designates the Department of Health and Environmental Control to serve as the sole state agency for administering the CON program and licensing health facilities.

State CON programs vary widely in terms of purpose and the extent to which they regulate health services. Each state has different economic thresholds for requiring a CON, and the list of services requiring CON review varies from state to state. Differences among individual state programs also include the quality and timeliness of the State Health Plan and the rigor with which regulations are enforced.

In states where the role of CON has been narrowed, the trend has been to streamline the process and raise the expenditure threshold to decrease the number of projects reviewed. In states where the role of CON has been broadened, certain actions previously exempted from CON have been included. For example, Michigan's CON law was extended to all providers for 13 specific types of equipment or services. Typically, hospitals have supported these types of expansions because they place hospitals on a level playing field with other niche or specialty providers.

## CON IN SOUTH CAROLINA

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The purposes of the South Carolina Certificate of Need law are to promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services that will best serve public needs, and ensure that high quality services are provided in health facilities in the state. South Carolina's CON Program has been in effect since 1971. Regulation No 61-15 requires the South Carolina Department of Health and Environmental Control (DHEC), with the advice of the South Carolina State Health Planning Committee, to prepare a State Health Plan for use in the administration of the CON Program. The DHEC Division of Planning and Certification of Need within the Bureau of Health Facilities and Services Development administers the CON Program.

## STATE HEALTH PLANNING COMMITTEE

The State Health Planning Committee is composed of fourteen members. Twelve are appointed by the Governor, with at least one member from each congressional district. Health care consumers, health care financiers (including business and insurance) and health care providers are equally represented. One member is appointed by the Chairman of the Board of DHEC, and the State Consumer Advocate is an ex-officio member. The State Health Planning Committee works with the DHEC staff to write the State Health Plan and submit it to the DHEC Board for final revision and approval.

## STATE HEALTH PLAN

At least once every two years, a revised State Health Plan must be submitted by DHEC staff and the State Health Planning Committee to the DHEC Board for adoption. The State Health Plan must include projections and standards for specified health services and equipment that have the potential to substantially impact health care cost and access. Planning standards incorporated into the State Health Plan are consistent with recommended medical and other professional standards. At a minimum, the State Health Plan must include:

- an inventory of existing health care facilities, beds, specified health services, and equipment;
- projections of need for additional health care facilities, beds, health services, and equipment;
- standards for distribution of health care services including scope of services to be provided, utilization, and occupancy rates, travel time, regionalization, etc.;
- a general statement as to the project review criteria considered most important in evaluating CON applications for each type of service; and
- a general statement as to whether the benefits of improved accessibility to each type of service may outweigh the adverse affects caused by the duplication of any existing service.

DHEC may not issue a CON unless the proposed project is in compliance with the currently approved State Health Plan.

## CURRENT SOUTH CAROLINA CON PROGRAM

Under current South Carolina law, an individual or health care facility is required to obtain a CON from DHEC before:

- constructing or otherwise establishing a new health care facility;
- adding one or more beds or changing the licensure classification of one or more beds;
- expending more than \$2 million on behalf of a health care facility;
- offering a new health service with an annual operating cost in excess of \$1 million;
- acquiring medical equipment costing in excess of \$600,000;
- acquiring or changing ownership or controlling interest of a health care facility; or
- adding or substantially expanding a health service for which specific standards are prescribed in the State Health Plan.

The following health services currently are covered by CON in South Carolina.

- |                                  |                                      |                     |
|----------------------------------|--------------------------------------|---------------------|
| ▪ Acute care                     | ▪ Gamma knife                        | ▪ Substance abuse   |
| ▪ Neonatal intensive care        | ▪ Magnetic resonance imaging (MRI)   | ▪ Rehabilitation    |
| ▪ Ambulatory surgical facilities | ▪ Positron Emission Tomography (PET) | ▪ Nursing home      |
| ▪ Cardiac catheterization        | ▪ Freestanding emergency services    | ▪ Home health       |
| ▪ Open heart surgery             | ▪ Psychiatric services               | ▪ Inpatient hospice |
| ▪ Linear accelerators            |                                      |                     |

CON requirements do not apply to all providers or to all health care projects in South Carolina.

Following is a list of projects and providers not subject to South Carolina's CON law.

- Offices of licensed private practitioners, whether for individual or group practice
- Non-medical projects, such as refinancing existing debt, roof replacement, parking garages, and computer systems
- Upgrades to facilities that do not include additional square feet or additional health services
- Replacement of similar equipment with comparable capabilities
- Purchases of or agreements to purchase real estate
- The acquisition, obligation of the capital expense or offering of an institutional health service solely for research
- Permanent reduction in bed capacity
- Facilities owned and operated by the federal government
- Federal facilities operated by the state
- Educational and penal institutional infirmaries for the exclusive use of their populations
- Facilities owned and operated by the South Carolina Department of Mental Health and the South Carolina Department of Disabilities and Special Needs except for the addition of total beds
- Change in ownership which does not result in increased depreciation or interest cost or lease cost greater than depreciation and interest cost added together or government reimbursement

DHEC evaluates and modifies the CON program and guidelines through legislation and policy implementation. The exemptions listed above have been made in an effort to streamline the approval process for minor construction and renovation projects by health care facilities. Project descriptions and cost estimates still must be submitted to DHEC for such exempted projects.

## OTHER STATES' EXPERIENCES

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*Minnesota* eliminated CON in 1984, replacing the law with a moratorium on the construction of new hospitals and expansion of existing hospital bed capacity. Provisions in the 1994 MinnesotaCare law require health care providers to report all major capital spending commitments exceeding \$1 million to the state for retrospective review, which assesses the project's appropriateness in terms of its impact on health care cost, quality, and access. In 2006, rising concern about the growth in medical facility investment and its impact on health care cost and utilization led Minnesota's legislature to request a study of the facility construction and expansion approval process. Several bills have been introduced to better regulate facilities as a result.

*Pennsylvania* allowed its CON statute to sunset in 1996, somewhat by accident. Since then, the number of niche providers, including imaging centers, specialty services, and ambulatory surgery centers, has increased dramatically, and the growth of services and technology has resulted in increased utilization and spending.

- Since 2000, the number of ambulatory surgery centers licensed in Pennsylvania has risen from 104 to 245.
- Forty-eight of those centers opened during the same year and patient visits during that period jumped 83%.
- Pennsylvania's ambulatory surgery utilization rates are 36 percent higher than the national average.
- Visits to ambulatory surgery centers increased 83% from 2001 to 2003.

Legislation to reestablish CON has been introduced in both the Pennsylvania House and Senate.

*Ohio* repealed its CON program in 1995 for all facilities, services, beds, capital, and equipment, except for long term care facilities. Services including cardiac catheterization, open heart surgery, obstetrics and newborn, radiation therapy, pediatric ICU, solid organ transplantation services, bone marrow and stem cell transplant programs are now subject to quality review, similar to a licensure program. Ohio has seen significant expansion of capacity for



previously regulated services and facilities, while critical money-losing services have suffered. Within just four years of deregulation:

- fifteen hospitals located in low-income areas closed;
- the number of imaging centers in Ohio increased by 748 percent, from 27 to 229;
- the number of ambulatory surgery centers increased 563 percent, from 27 to 179, and the majority of new ambulatory surgery centers are being built in affluent and growing suburbs, and are physician-owned;
- the number of non-hospital-based mobile or freestanding MRIs increased from 23 to 126 in 30 months, and another 65 notices of intent were filed.

*Indiana* enacted CON laws in 1980 and terminated them in 1996, reenacted them in 1997 before terminating them again in 1999. Since then, the CON debate has languished in the state's General Assembly and at the county level. Four counties with county-owned hospitals enacted a moratorium on new health service construction, and lawsuits were filed in U.S. District Court against three of these counties by other hospitals and developers. County officials claimed they needed to make sure their county-owned hospitals remained viable in the face of more development. They also argued that specialty providers wanted to enter their turf and cherry-pick profitable services. To illustrate that, county officials pointed to the fact that between 2000 and the middle of 2002, four heart hospitals and one orthopedic hospital opened, were under construction or were in the planning stages in Indianapolis—a metropolitan area of 1.6 million people. They feared the loss of these profitable services would endanger their ability to provide other services such as emergency rooms, trauma centers, and neonatal intensive care. Developers contended the counties are protecting monopolies and did not have the power to enforce such restrictions. In 2005, a federal court ruled against one county's attempt to protect its community hospital, declaring that only the state has the right to license and regulate hospitals.

*Missouri* phased out significant portions of its CON program in 2001, leaving only nursing homes, residential care beds, long-term acute beds, and the construction of new hospitals subject to CON review. This resulted in so many proposals for facilities that a backlog ensued. Legislation to further restrict the CON process, restrict the development of specialty hospitals and repeal CON has been introduced in recent years, but has not been successful. In 2006, the Missouri Senate formed an interim committee to evaluate CON, and the state maintains its program today.

In 2004, *Florida* implemented the most significant CON reform since 1986. The single most important component of the reform was a provision preventing the licensure of niche and specialty hospitals. CON was eliminated for interventional cardiology and open heart surgery, but legislators concerned about the continued proliferation of niche providers set in place certain quality standards that must be demonstrated by all providers offering these services. The law also eliminated CON for burn units, as well as for additional acute care, mental health, and neonatal intensive care beds at existing hospitals. Legislation passed in 2008 further streamlines the CON process and includes a “loser pays” provision to discourage lawsuits designed to delay the launch of new facilities.

In *Georgia*, the State Commission on the Efficacy of the Certificate of Need Program recommended that CON be maintained and improved after spending 18 months examining the role of CON. The final Commission report issued in December 2006 stated, “The Commission has been able to reach consensus on a number of ways to improve upon Georgia's Certificate of Need Program. However, sharp disagreement remains with regard to a number of areas of regulation, most notably, regulation of ambulatory surgery centers and free-standing imaging centers.”

## **WHY SOUTH CAROLINA NEEDS A STRONG CON PROGRAM**

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### **HEALTH CARE IS DELIVERED IN A HIGHLY REGULATED ENVIRONMENT, MAKING FREE MARKET FORCES INEFFECTIVE**

Opponents of CON continue to argue that the best way to assure quality, efficiency, access, innovation, and lower prices is to rely on competition and market forces—the cornerstones of a free market. This argument appeared again

in a Fall 2004 report from the Federal Trade Commission entitled “*Improving Health Care: A Dose of Competition*.” The executive summary of the report concluded with the following statement:

“The fundamental premise of the American free-market system is that consumer welfare is maximized by open competition and consumer sovereignty—even when complex products and services such as health care are involved. . . The Agencies do not have a pre-existing preference for any particular model for the financing and delivery of health care. Such matters are best left to the impersonal workings of the marketplace.” *Improving Health Care: A Dose of Competition, Executive Summary, p.11.*

Yet health care delivery is not provided in the “impersonal working of the marketplace.” It is provided in local communities by community-oriented hospital systems and providers, and it reflects community values and needs. Additionally, it is provided in a highly regulated and controlled environment that is not consistent with a free market. As a result, the presumed beneficial effects of competition are not achievable in the health care system unless the following barriers to a “free market” are removed:

- the requirement that hospitals must provide care in all urgent and emergent circumstances regardless of the patients’ ability to pay for those services;
- legislatively mandated health care services;
- legislatively mandated health insurance benefits;
- third party payer influence in provider and service selection;
- mandated payment rates for services provided to Medicare and Medicaid beneficiaries;
- and
- physician control of services received by patients.

Unless these barriers are removed or changed, community-based planning, licensure and CON regulation will be needed to ensure that services will be available to meet the needs of South Carolina’s citizens.

## CON HELPS CONTAIN HEALTH CARE COSTS

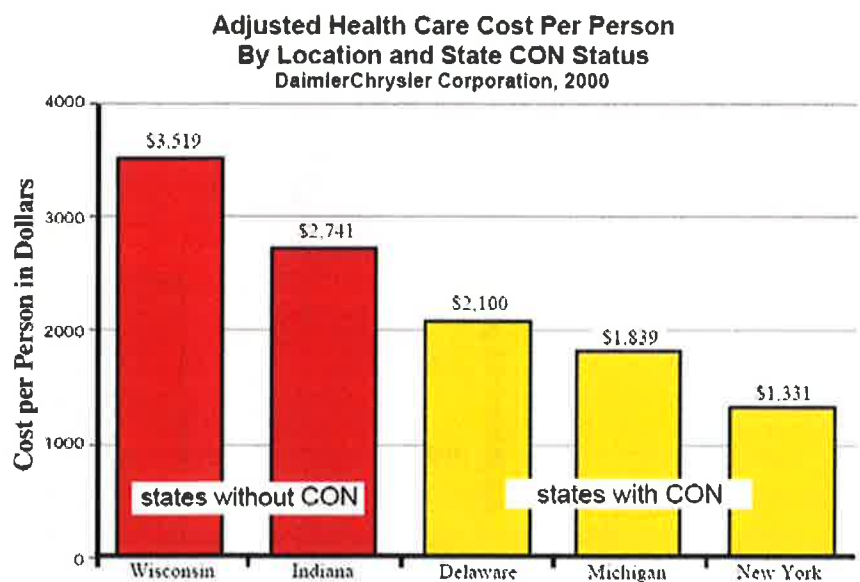
Many business leaders regard hospital expansions and the proliferation of high-cost technology as a primary reason health care costs are increasing. CON discourages the proliferation of duplicative facilities, services and equipment.

While some might argue that deregulating health facility and service expansion will trigger free market forces of supply and demand and lead to lower costs, three major automobile manufacturers—General Motors Corporation, Ford Motor Company, and DaimlerChrysler Corporation (now Daimler AG)—have not found that to be true based on experiences in states that have varying degrees of CON regulation. Independent studies conducted by all three of these multi-state corporations with similar benefit plans consistently found that the costs of health care per person were significantly less in states with CON than in states without CON.

The following conclusions from those studies are particularly revealing.

From DaimlerChrysler Corporation (DCC) –

- In DCC’s traditional and PPO programs, the costs of health care per person are significantly less in states with CON programs than in states without CON. What is notable

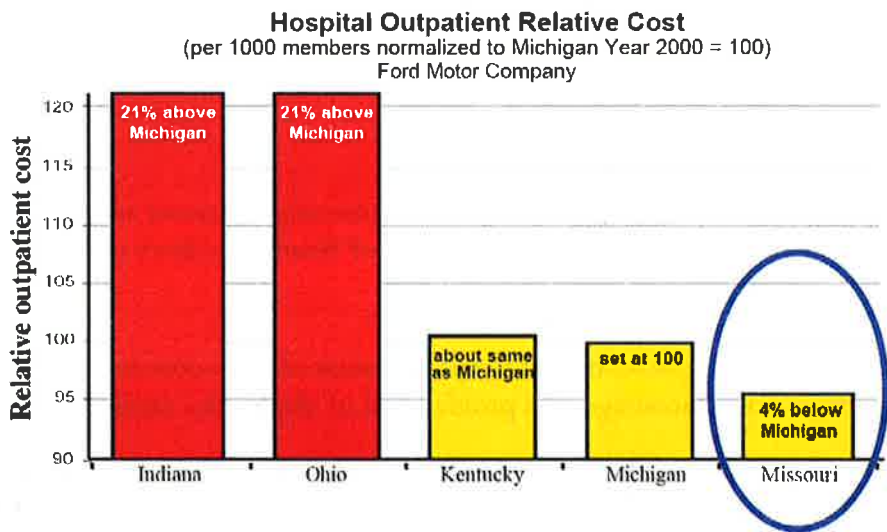


is that the design of DCC's health benefit programs does not vary by geographic region and that significant differences in relative costs occur between areas even after the data is standardized for gender and age. DCC's costs for health care are considerably higher in non-CON states, such as Wisconsin and Indiana, than in CON states such as Delaware, Michigan and New York.

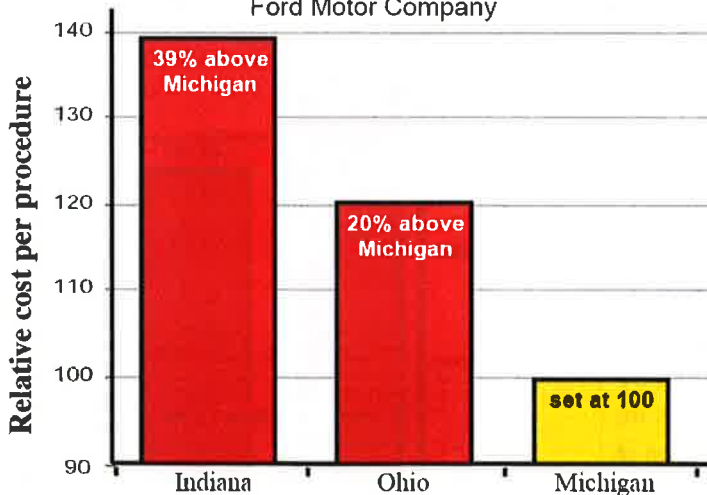
- DCC's three lowest cost areas are in states with CON laws in place, while the two highest cost areas are in the state without CON laws.

From Ford Motor Company –

- Indiana and Ohio, which eliminated CON coverage for most services, consistently had the highest relative costs.
- Michigan, with a CON program since 1972 covering a wide range of services, consistently had among the lowest relative costs.
- Kentucky and Missouri, which also have had CON programs covering a wide range of services, also had low relative costs.
- This consistent correlation between CON and lower costs was quite notable because the pattern was the same across a range of different services. This was true for the broad but differing categories of hospital inpatient and outpatient services, and the narrower focus on CABG (an inpatient surgical procedure) or on MRI (a diagnostic service, mostly done on an outpatient basis).



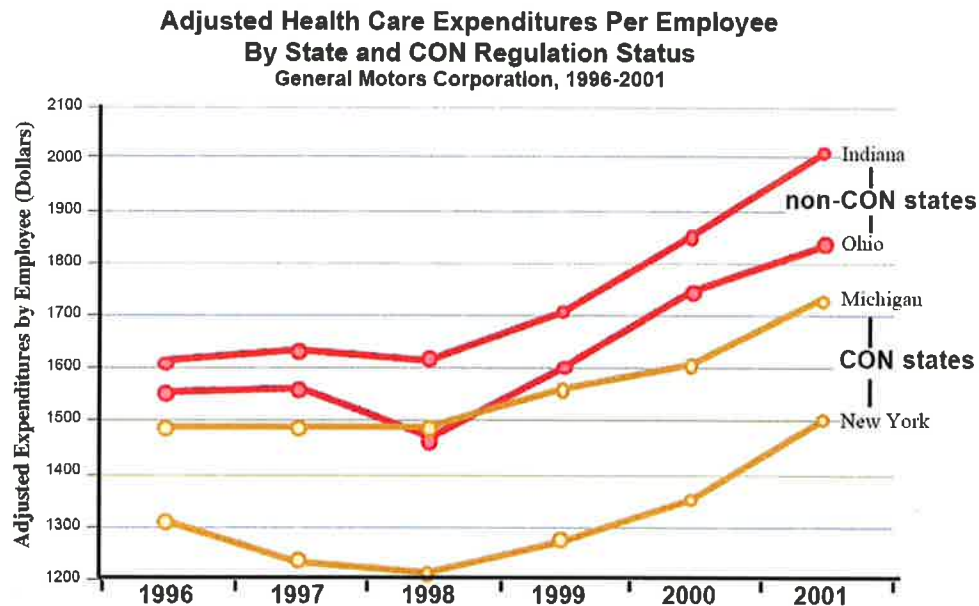
**Coronary Artery Bypass Graft (CABG) Surgery**  
**Relative Cost Per Service**  
(per 1000 members normalized to Michigan Year 2000 = 100)  
Ford Motor Company





From General Motors Corporation (GM) –

- “At GM, we believe that improving health care quality will reduce costs. It is a continual effort to balance quality, access and costs, but we believe it can be done through delivering the right services, for the right patients, at the right time. We believe improving quality means preventing overuse, under use and misuse of the health care system by reducing unnecessary, duplicative and wasteful services. We strongly believe in fostering the same kind of continuing quality improvement efforts in the medical community that we apply to our own business. We do not believe that unbridled expansion of health care services will lead to improved quality, affordability or accessibility.”
- While the GM populations served and the benefits and cost-saving provisions are quite similar in all four states, their health care costs were highest in Indiana—a state with no CON regulation—and lowest New York—a state with stringent CON regulation.



A Stanford University study published in *Health Affairs* evaluated the relationship between the supply of new technologies and health care utilization and spending, focusing on diagnostic imaging, cardiac, cancer, and newborn care technologies. The study found that increases in the supply of technology tend to be related to higher utilization, as evidenced in states like Pennsylvania and Ohio after CON was repealed.

### LOOPHOLES IN CON PROGRAMS CAN CAUSE INEQUITIES

With national spending levels estimated at \$100 billion annually, diagnostic imaging has become a major factor in the cost of health care in the United States, second only to pharmaceuticals for most health plans. There is evidence that this growth in spending is linked to the proliferation of imaging centers being developed as “private physician offices,” which are typically exempted from CON.

- The American College of Radiology (ACR) indicates that the number of MRI procedures in the U.S. jumped from about 7.4 million in 1995 to 23.7 million in 2005, and is expected to reach 34 million by 2010.
- Although hospitals already have imaging equipment and capacity, studies show that imaging procedures are being moved out of hospitals. The Radiological Society of North America (RSNA) reported that between 1997 and 2002 the proportion of noninvasive diagnostic imaging performed in hospitals fell from 33.6% to 28.4% while imaging at private offices and freestanding centers rose from 28.1% to 32.6%.
- A study in 2008 using Medicare Part B claims data found that while private office imaging utilization rates between 1996 and 2006 grew by 63%, those rates in hospital outpatient departments grew by 25%. About 60% of all diagnostic imaging procedures are performed in private offices.

- The American Health Planning Association found that residents in states with CON have lower MRI use rates than residents of states without CON. Community hospitals in states with CON programs also have a larger share of MRI services than community hospitals in states without CON.

Any further loosening of CON requirements for MRI facilities would only lead to significant proliferation of such facilities, additional duplication, overuse, and rising health care costs.

## CON HELPS PROTECT ACCESS TO SERVICES

CON ensures the financial health of safety net hospitals caring for South Carolina's communities by restricting the development of "boutique hospitals" which tend to offer lucrative services to insured patients. When boutique hospitals siphon off the community hospital's insured patients and refuse to offer low-revenue services, safety net hospitals are forced to provide a higher percentage of low-revenue procedures, substantially compromising their ability to provide charity care.

In 2003, Congress imposed an 18-month moratorium on the development of new physician-owned specialty hospitals due to concerns about their negative impact on community hospitals. In 2005 and 2006 reports to Congress, the Medicare Payment Advisory Commission (MedPAC) found that physician-owned specialty hospitals treat fewer severely ill patients and concentrate on particular DRGs which are relatively more profitable. The report also found these specialty hospitals are often located in states without CON laws, are less likely to have emergency departments, and treat a lower percentage of Medicaid patients.

In states without CON, providers will tend to reduce services to rural, inner city, and high/special needs areas and locate in more affluent, profitable areas. Currently all CON applications in South Carolina must include detailed plans of access to care for the indigent population. There is anecdotal evidence that the provision of charity care may be greater in states that maintain CON requirements when it is a stipulation of CON.

## CON HELPS SAFEGUARD QUALITY OF HEALTH CARE SERVICES

CON helps maintain service quality by limiting the number of locations in which specialized and high risk medical procedures may be performed. CON encourages the development of specialized regional health care services, which leads to more cases per provider, better treatment outcomes (e.g., lower mortality), more cost-effectiveness, and the development of more comprehensive and capable service programs.

After allowing its CON law to expire in 1996, Pennsylvania experienced dramatic growth in the number of open heart surgery programs, which increased from 35 to 62. However, volume of cases per hospital dropped from 499 in 2000 to 330 in 2006—fewer than the 450 bypasses per year recommended by the Leapfrog Group, a national coalition of employers working to improve quality of health care.

Researchers at the University of Iowa studying more than 900,000 cases of open heart surgery found that the volume of procedures per program was 84 percent higher in CON states and the odds of death were 22 percent lower for patients receiving coronary artery bypass graft (CABG) surgery in states with CON regulation as compared to similar patients in non-regulated states. Mortality rates were lower in CON-regulated states during the entire six-year period and in each year covered by the study. According to this study, the difference between CON and non-CON states is nine preventable deaths for every 1,000 procedures. Based on their conclusion, South Carolina's CON program is saving the lives of 54 bypass patients each year.

## CONCLUSION

The empirical evidence is clear. While CON is not a perfect system, it is the best approach available to protect community resources and safeguard access to care and quality of services. Therefore, the South Carolina Hospital Association strongly supports the continuation and improvement of our state's CON program.

*September 2005 updated February 2009*

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South Carolina Hospital Association  
1000 Center Point Road | Columbia, SC 29210  
P 803.796.3080 | F 803.796.2938  
[www.scha.org](http://www.scha.org)